

## **REMARKS/ARGUMENTS**

### **Summary of the Examiner's Actions**

The examiner objected to the drawings for various informalities. Applicant acknowledges such objections, and appreciates the thorough review of the drawings.

The examiner rejected Claims 15 and 16 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention. Applicant acknowledges the rejection under 35 U.S.C. § 112, second paragraph.

The examiner rejected Claims 17-19 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application No. US 2003/0234194 ("the '194 application"), filed by Clark *et al.*, in view of U.S. Letters Patent No. 4,901,852 ("the '852 patent"), issued to King. Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claim 20 under 35 U.S.C. § 103(a) as being unpatentable over the '194 application and the '852 patent as applied to Claim 17 above, and further in view of U.S. Letters Patent No. 6,224,543 ("the '543 patent"), issued to Gammons *et al.* Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claims 1-16 under 35 U.S.C. § 103(a) as being unpatentable over the '194 application and the '852 patent as applied to Claim 17 above, and further in view of the '543 patent, or U.S. Letters Patent No. 3,954,049 ("the '049 patent") issued to Brieske. Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

### **Objections to the Drawings**

The examiner objected to the drawings under 37 CFR 1.83(a), stating that the drawings must show every feature of the invention specified in the claims. The examiner indicated that the "curved transition" of Claims 5, 11 and 13 must be shown or the features cancelled from the claims.

In reviewing the specification and the claims, it is noted that what is disclosed, at page 9, lines 4-5, is “an uninterrupted portion of a second shoulder segment **56** (see Fig. 1).” Accordingly, Claims 5, 11 and 13 have been amended as indicated above to more properly claim “an uninterrupted transition”. It is respectfully submitted that the contrast is being made between a transition that defines a scalloped edge **54** and one that does not, or is “uninterrupted,” and the expansibility of the first as opposed to the latter. Accordingly, it is respectfully submitted that the particular configuration is not what is being claim, with the exception that it is void of a scalloped edge **54**.

It is respectfully submitted, then, that the applicant has overcome the examiner’s objection to the drawings, and that no new matter has been added.

#### **Rejections under 35 U.S.C. § 112, second paragraph**

The examiner rejected Claims 15 and 16 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention. Specifically, the examiner rejected Claim 15 as having insufficient antecedent basis for the limitation “said carrier” in line 3. The examiner rejected Claim 16 as having insufficient antecedent basis for the limitation “said carrier” in lines 1-2.

Claims 15 and 16 have each been amended to include the limitations found in Claim 2. Specifically, each of Claims 15 and 16 has been amended to include the limitation that the sheath further comprises “a carrier for receiving said sheath thereon, said sheath being releasably mounted to said carrier along at least a portion of said contoured perimeter of said sheath by said means bonding, whereby said sheath is removed from said carrier when the controller is disposed within the sheath.”

Accordingly, it is respectfully submitted that the examiner’s rejection under 35 U.S.C. § 112, second paragraph, has been overcome.

#### **Rejections under 35 U.S.C. § 103(a)**

In order to support a rejection under 35 U.S.C. § 103(a), “the examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness.”

MPEP § 2142, pg. 2100-121, 8th ed. “To reach a proper determination under 35 U.S.C. § 103(a), the examiner must step backward in time and into the shoes worn by the hypothetical ‘person of ordinary skill in the art’ when the invention was unknown and just before it was made.” *Id.* The first element in establishing a *prima facie* case of obviousness is that “there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings.” MPEP § 2143, pg. 2100-122, 8th ed. The second element is that there “must be a reasonable expectation of success.” *Id.* The third element is that “the prior art reference (or references when combined) must teach or suggest all the claim limitations.” *Id.*

The relevant facts for finding obviousness relate to (1) the scope and content of the prior art, (2) the level of ordinary skill in the field of the invention, (3) the differences between the claimed invention and the prior art, and (4) any objective evidence of nonobviousness such as long felt need, commercial success, the failure of others, or copying. *Graham v. John Deere Co.*, 148 U.S.P.Q. 459, 467 (1966; see *Continental Can Co. v. Monsanto Co.*, 20 U.S.P.Q.2d 1746, 1750-51 (Fed. Cir. 1991). The Supreme Court in *Graham* stated that “the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.” *Graham*, 383 U.S. at 17, 148 U.S.P.Q. at 467. The *Graham* court further stated that “[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.” *Id.*

The examiner rejected Claims 17-19 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application No. US 2003/0234194 (“the ‘194 application”), filed by Clark *et al.*, in view of U.S. Letters Patent No. 4,901,852 (“the ‘852 patent”), issued to King.

Clark *et al.*, disclose a disposable shield designed to sheath a patient control unit prevents contaminants from contacting or entering the patient control unit. Bubbles are formed in the shield to cover the controls on the control unit so that they

can be operated through the shield. Clark *et al.*, specifically teach that the shape of the '194 device "generally matches the shape of the control unit **102** so that the shield **100** will conform to the control unit's **102** shape without leaving any undesired gaps between the shield **100** and the unit **102**." (see paragraph [0011]). Clark *et al.*, further teach that the shield is cast or molded (see Paragraph [0014]) and that "the shield **100** is preferably seamless, with no cracks or crevices that could trap contaminants."

King discloses a protective cover for pagers formed to cover the top, four sides, and at least a portion of the bottom of a pager. The cover includes accordion type pleats which are positioned to reside adjacent switches, a belt clip, and the like, to allow operation thereof. As described at col. 2, lines 40-44, the preferred methods of forming the cover are by injection or compression molding. The King device is lacking of seams, as in the Clark *et al.*, device.

The Examiner indicated that Clark *et al.*, disclose a tubular sheath of flexible material having an open end, a nose end, a perimeter, and a first and second shoulder segment, and that they merely lack a scalloped shoulder. The examiner then indicated that King discloses a scalloped shoulder, and that it would be obvious to combine these two references in order to read on the subject matter of Claim 17. Similar reasoning was given in rejecting Claims 18 and 19. However, it is respectfully submitted that the scalloped shoulder of the present invention and the pleats taught by King are patentably distinct. To wit, the scalloped shoulder of the present invention is configured to be expandable to receive a switch as described. The size and shape of the switch is not considered here, in that the scalloped shoulder is expandable to meet the requirements of several different hand-held devices. In the King device, the pleats are specifically configured for a particular device. The pleats of the King device are not expandable as the scalloped shoulders of the present invention. Accordingly, it is respectfully submitted that Claim 17 as originally presented is in condition for allowance.

Notwithstanding, it is respectfully submitted that Clark *et al.*, and King fail to either individually or in combination anticipate or make obvious the limitations of Claim 17 as amended. Specifically, the present invention is drawn toward a sheath

that is fabricated from two overlying sheets of material that are welded along a portion of their respective perimeters to form an open end for receiving a hand-held device. Claim 17 has been amended to include the limitation that the tubular sheath includes top and bottom flexible panels having contoured perimeters and being bonded to one another along a portion of the respective of contoured perimeters.

Accordingly, it is respectfully submitted that the examiner's rejection of Claims 17-19 under 35 U.S.C. § 103(a) has been overcome.

The examiner rejected Claim 20 under 35 U.S.C. § 103(a) as being unpatentable over the '194 application and the '852 patent as applied to Claim 17 above, and further in view of U.S. Letters Patent No. 6,224,543 ("the '543 patent"), issued to Gammons *et al.*

Gammons *et al.*, disclose a device for covering an elongated medical probe such as a vaginal, rectal, ultra sound or the like type probe. In the preferred embodiment the sheath is tubular and includes a nose and an open end through which the medical probe is inserted. Preferably the sheath is packaged by mounting it on a flexible carrier in a partially elongated position. An adhesive material releasably secures the sheath to the carrier such that the nose of the sheath is inverted and defines a folded nose opening to facilitate positioning the sheath over the tip of a conventional medical probe.

The applicant of the present invention is the first-named inventor in the Gammons *et al.*, patent. Applicant is not claiming the invention here as being a sheath formed on a carrier, but that of the specific sheath as claimed being manufactured and transported on a carrier. It is respectfully submitted, though, that Clark *et al.*, and King teach away from such a combination, as each discloses a device which is preferably molded or cast, and that, as specifically stated by Clark *et al.*, define no seams. It is respectfully submitted that the cited art, though related in the sense that they each are provided for covering a device to maintain a sterile field, are divergent technologies at the level of their respective structures.

Accordingly, it is respectfully submitted that the examiner's rejection of Claim 20 under 35 U.S.C. § 103(a) has been overcome.

The examiner rejected Claims 1-16 under 35 U.S.C. § 103(a) as being unpatentable over the '194 application and the '852 patent as applied to Claim 17 above, and further in view of the '543 patent, or U.S. Letters Patent No. 3,954,049 ("the '049 patent") issued to Brieske.

Brieske discloses a flexible bag construction and a method for producing the bag. The construction is formed from flexible plastic films located in overlying relationship with one film defining a return portion having a free edge positioned inwardly from the top of the bag. A second free edge is defined by a separate film portion in spaced relationship relative to the first free edge. A flexible plastic strip is introduced between the return portion and the opposing film and this strip is heat sealed in place.

As in the rejections of Claims 17-20 as discussed above, it is respectfully submitted that the Clark *et al.*, King and Gammons *et al.*, patents teach away from each other to the extent that Clark *et al.*, specifically teaches against forming seams for the purpose of eliminating those areas where contaminants might become trapped. Further, King discloses a similar construction to that of Clark *et al.*, in that no seams are formed. However, Gammons *et al.*, and Brieske specifically teach the use of seams in their construction processes. Accordingly, it is respectfully submitted, again, that there is no motivation to combine these divergent construction methods.

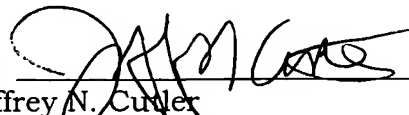
Accordingly, it is respectfully submitted that the examiner's rejection of Claims 1-16 under 35 U.S.C. § 103(a) has been overcome.

### **Summary**

In view of the amendment of Claims 5, 11, 13 and 15-17, and the arguments presented herein, it is believed that the above-identified patent application is in a condition for the issuance of a Notice of Allowance. Such action by the examiner is respectfully requested. If, however, the examiner is of the opinion that any of the drawings or other portions of the application are still not allowable, it will be appreciated if the examiner will telephone the undersigned to expedite the prosecution of the application.

Please charge any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 16-1910.

Respectfully submitted,  
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